delegated to her (21 CFR 5.82), finds that new evidence of clinical experience not contained in the application and not available until after the supplement to the application for the indication was approved, evaluated together with the evidence available when the supplement to the application for the indication was approved, shows that bromocriptine is not shown to be safe for the prevention of physiological lactation upon the basis of which the indication was approved (21 U.S.C. 355(e)(2)).

Therefore, pursuant to the foregoing finding, approval of the indication is hereby withdrawn, effective February 16, 1995.

Dated: December 27, 1994.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 95–1074 Filed 1–13–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPD–778–FN]

RIN 0938–AG28

Medicare Program; Special Payment Limits for Home Blood Glucose Monitors

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final notice.

SUMMARY: This notice establishes special payment limits for standard home blood glucose monitors, identified as code E0607 of the HCFA Common Procedure Coding System (HCPCS). This final notice is intended to prevent excessive payment for these items. Currently, payment under the Medicare program for home blood glucose monitors and other items of durable medical equipment (DME) is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. This notice requires that payment for standard home blood glucose monitors be equal to 80 percent of the lesser of the actual charge or a special payment limit.

DATES: This notice is effective February 16, 1995.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 966–4499.

SUPPLEMENTARY INFORMATION:

I. Background

A. Special Reasonable Charge Limits

Payment for DME furnished under Part B of the Medicare program (Supplementary Medical Insurance) is made through contractors known as carriers. Before January 1, 1989, payment for DME was made on a reasonable charge basis. The methodology used by the carriers to establish reasonable charges is set forth in sections 1833 and 1842(b) of the Social Security Act (the Act) and in 42 CFR part 405, subpart E. Reasonable charge determinations are generally based on customary and prevailing charges derived from historic charge data. The reasonable charge for an item of DME was generally set at the lowest of the following factors:

- The supplier's actual charge for the item.
- The supplier's customary charge.
- The prevailing charge in the locality for the item.

(The prevailing charge may not exceed the 75th percentile of the customary charges of suppliers in the locality.)

- The inflation indexed charge (IIC).

The IIC is defined in § 405.509(a) as the lowest of the fee screens used to determine reasonable charges for services, supplies, and equipment paid on a reasonable charge basis (excluding physicians' services) that is in effect on December 31 of the previous fee screen year, updated by the inflation adjustment factor.

Section 1842(b)(3) of the Act requires that all payments made under Part B of the Medicare program must be reasonable. Paragraphs (8) and (9) of section 1842(b) of the Act provide that we may establish a special reasonable charge limit for a category of service if, after consultation with representatives of affected parties, we determine that the standard rules for calculating reasonable charges result in grossly deficient or excessive charges.

Applicable regulations are located at § 405.502(g). Section 405.502(g) requires that we consider the available information that is relevant to the category of service and establish reasonable charge limits that are realistic and equitable. The limit on the reasonable charge is an upper limit to correct a grossly excessive charge or a lower limit to correct a grossly deficient charge. The limit is either a specific dollar amount or is based on a special method to be used in determining the reasonable charge.

B. DME Fee Schedules

Section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100–203), which added section 1834(a) to the Act, provides for a fee schedule payment methodology for DME furnished on or after January 1, 1989. (This fee schedule payment methodology is set forth in 42 CFR part 414, subpart D.) Sections 1834(a)(1)(A) and (B) of the Act provide that Medicare payment for DME is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. Section 1834(a) of the Act classifies DME into the following payment categories:

- Inexpensive or other routinely purchased DME.
- Items requiring frequent and substantial servicing.
- Certain customized items.
- Oxygen and oxygen equipment.
- Other items of DME (capped rental items).

There is a separate methodology for determining the fee schedule payment amount for each category of DME. The fee schedules are adjusted annually by a covered item update factor. The covered item update factor is generally equal to the change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending June 30 of the preceding year.

Section 1834(a)(10)(B) provides that we may apply the special payment limits authority of paragraphs (8) and (9) of section 1842(b) to covered items of DME and suppliers of these items and payments under section 1834(a) in the same manner as these provisions apply to physician's services and physicians and reasonable charges under section 1842(b).

C. Payment for Home Blood Glucose Monitors (Code E0607)

Standard home blood glucose monitors allow individuals to measure their blood glucose and, then, alter their diets or insulin dosages to ensure that they are maintaining an adequate blood glucose level. Home blood glucose monitors are covered by the Medicare program as DME and are classified under the inexpensive and other routinely purchased DME payment category defined in section 1834(a)(2) of the Act. Section 1834(a)(2) specifies that inexpensive and other routinely purchased DME are those items of DME that have a purchase price that does not exceed $150 or are acquired at least 75 percent of the time by purchase. We determined that home blood glucose monitors belong in this category based on a review of data that show that these monitors are acquired at least 75 percent of the time by purchase.

Section 1834(a)(2) requires that payment for items falling within this category be made on a purchase or rental basis and that local purchase and rental fee schedule amounts be calculated for each item. Section 414.220(c)(1) provides for the calculation of purchase fee schedules

for both new and used DME within this category. The fee schedule amounts for purchased new, purchased used, and rental DME within this category are based on the average reasonable charges for purchased new, purchased used, and rental DME, respectively, from the base year period of July 1, 1986 through June 30, 1987.

II. Summary of the Proposed Notice

We published a proposed notice in the **Federal Register** on January 6, 1994, (59 FR 755) to announce our intention to establish special payment limits for standard home blood glucose monitors.

We had anticipated that the proposed notice would be published during calendar year (CY) 1993 and we used CY 1993 information to calculate the proposed special payment limits for home blood glucose monitors. We proposed the following special payment limits for a home blood glucose monitor furnished before January 1, 1994:

- For a new monitor furnished to Medicare beneficiaries in the continental U.S., the upper payment limit would be $57. In Alaska, Hawaii, Puerto Rico, and the Virgin Islands, the upper payment limit would be $65.
- For a used monitor, the upper payment limit would be 75 percent of the special payment limit for a purchased new monitor. If the special payment limit for a purchased new home blood glucose monitor in the continental U.S. would be $57, the special payment limit for the used monitor would be $42.75.
- For a rented monitor, the special payment limit would be equal to 10 percent of the special payment limit for a purchased new monitor. The total payment for a rented monitor would not be allowed to exceed the lower of the actual charge or the fee for the purchase of the monitor.

In the preamble to the proposed notice (59 FR 756), we described how the 1993 fee schedule amounts for code E0607 accurately reflected the average reasonable charges for home blood glucose monitors in 1986, adjusted by 1.7 percent (the percentage increase in the CPI–U for the 6-month period ending with December 1987) and by the cumulative covered item update factor. The average 1993 fee schedule amount for purchased new home blood glucose monitors, excluding the fee schedule amounts for the Virgin Islands, Alaska, Hawaii, and Puerto Rico, was $178.73. However, as we explained in the proposed notice, due to manufacturers' widespread practice of issuing consumer rebates, the fee schedule amounts substantially exceeded the effective purchase amount (the list purchase amount less any rebate) paid by the general public in all localities.

In the proposed notice (59 FR 756), we discussed how we reviewed numerous sources of pricing and rebate information for the years 1986 through 1993. We also discussed our decision to focus on home blood glucose monitor pricing and national rebate programs listed in the Winter 1993 edition of the Bruce Medical Supply catalog (Vol. 15, No. 1). We explained that the Bruce catalog listed the largest number of home blood glucose monitors made by the largest number of home blood glucose monitor manufacturers, and reflected the national rebate programs offered by these manufacturers. Six different brands of home blood glucose monitors, manufactured by five different organizations, could be purchased from the Bruce catalog from any location in the United States, Puerto Rico, and the United States Virgin Islands and were covered under Medicare. We estimated that the six monitors listed in the Bruce Catalog accounted for approximately 90 percent of the market. By choosing the Bruce catalog as the source of data for proposing payment limits, we were not recommending that future purchases of home blood glucose monitors by Medicare beneficiaries be made through the Bruce catalog. We were confident, however, that comparable net prices were available in all localities from the various other mail order or retail outlets. Therefore, we believed that beneficiaries would have access to home blood glucose monitors for the payment limits we were proposing.

Our finding that new home blood glucose monitors are generally available to the general public at a net cost that is well below the fee schedule amounts proposed for code E0607 was supported by the Office of the Inspector General's (OIG) report ''Durable Medical Equipment—Review of Medicare Payments for Home Blood Glucose Monitors'' (A–09–92–00034)—issued in December of 1992. In this report, the OIG states that excessive Medicare payments have been made for home blood glucose monitors because claims were not adjusted to reflect manufacturers' rebates. The OIG reviewed a sample of 80 Medicare claims for monitors processed by 2 carriers. From this sample, the OIG identified 50 claims for which rebates were available at the time the monitors were purchased. The OIG found that Medicare payment for only 5 of these 50 claims were reduced by the amount of the rebate. The OIG concluded that the fee schedule amounts established for code E0607 based on pre-1987 historic charges were excessive.

A. Special Payment Limits for Code E0607

We proposed that payment for home blood glucose monitors be equal to 80 percent of the lesser of the actual charge for the monitor or the appropriate special payment limit as described below.

1. New Home Blood Glucose Monitors

For purchased new home blood glucose monitors furnished to Medicare beneficiaries, we proposed the following special payment limits:

INITIAL YEAR SPECIAL PAYMENT LIMITS

Continental U.S.	Alaska, Hawaii, Puerto Rico and Virgin Islands
$57	$65

These limits were based on pricing and manufacturers' rebates contained in the Winter 1993 edition of the Bruce Medical Supply catalog. We based the final limits for the continental U.S. on the median net cost, rounded to the nearest dollar, of five of the six monitors listed in the catalog. We omitted one monitor because this monitor was relatively new to the market and had little market history. We determined the cost for each monitor to be equal to the Bruce Medical Supply list price decreased by the manufacturer's mail-in rebate (if applicable) and increased by appropriate shipping and handling charges effective December 1992. After making the adjustments for rebates and shipping and handling charges, we proposed a limit of $57, which exceeded the final cost for four of the six monitors listed in the catalog. We permitted an additional shipping charge of $8 for monitors purchased in Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands.

In the proposed notice, we recognized that shipping and handling costs are unique to mail-order outlets and are not generally experienced by retail outlets; however, we chose to include these shipping and handling costs, without regard to the type of supplier, as a proxy for similar costs such as transportation and overhead that might be incurred by retail stores. The average shipping and handling cost per monitor in the continental U.S. is approximately $7, an amount that we believe sufficiently reflects expenses incurred by retail stores that supply home blood glucose monitors. The additional shipping allowance of $8 is intended to reflect additional costs of shipping outside the continental U.S.

2. Purchased Used Home Blood Glucose Monitors

Historically, the Medicare-allowed payment amounts for the purchase of used DME have been set at approximately 75 percent of the corresponding allowed payment amounts for the purchase of new DME. Based on this ongoing policy, for purchased used home blood glucose monitors, we stated in the proposed notice that the special payment limits would be equal to 75 percent of the special payment limits for purchased new monitors. If the special payment limit for a purchased new home blood glucose monitor would be $57, the special payment limit for the purchased used monitor would be $42.75.

3. Rented Home Blood Glucose Monitors

Historically, the Medicare-allowed payment amounts for the rental of DME have been set at approximately 10 percent of the corresponding allowed payment amounts for the purchase of new DME. Based on this ongoing policy, for rented home blood glucose monitors, the special payment limits under the proposed notice would be equal to 10 percent of the special payment limits for purchased new monitors. If the special payment limit for a purchased new home blood glucose monitor would be $57, the special payment limit for a rented monitor would be $5.70 each month. The total payment for a rented monitor would not be allowed to exceed the lower of the actual charge or the special payment limit for the purchase of the monitor.

B. Applicability

The initial special payment limits in the proposed notice would have applied to standard home blood glucose monitors furnished before January 1, 1994. (However, as noted above, the proposed notice was not published until after that date.) We proposed that, for standard home blood glucose monitors furnished in CY 1994, the special payment limits would be equal to the initial special payment limits increased by the 1994 covered item update factor (the factor used to update other items of DME). (The covered item update for 1994, and each subsequent year, is defined in section 1834(a)(14)(B) of the Act as the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.) For each calendar year after 1994, we proposed that the special payment limits would be equal to the special payment limits for the preceding calendar year increased by the covered item update for the calendar year to which the limits would apply.

These special payment limits would not apply to home blood glucose monitors with special features (HCPCS code E0609).

III. Supplier Consultation

Sections 1834(a)(10)(B) and 1842(b)(9)(A)(i) of the Act require that we consult with representatives of the suppliers likely to be affected by any change in payment before making a determination that a fee schedule amount(s) is not inherently reasonable by reason of its grossly excessive or deficient amount. In the proposed notice (59 FR 757), we discussed the meeting held on June 15, 1993, with representatives of suppliers of home blood glucose monitors (hereinafter referred to as supplier representatives). The purpose of the meeting was to discuss issues relating to Medicare payment for these devices. The supplier representatives were primarily concerned about the use of manufacturer rebate information in determining appropriate Medicare payment amounts for home blood glucose monitors. They maintained that the rebate programs were purely a marketing tool used by the manufacturers to promote the sale of their monitors, that the rebates do not relate in any way to the ''market price'' of the monitors, and that the rebate programs were not permanent and, therefore, should not be used as a basis for establishing payment amounts. The supplier representatives also maintained that some rebate programs are not available in some areas of the United States.

The OIG report, previously cited, stated that manufacturer rebates for home blood glucose monitors generally range from about $30 to $75 and that the duration of the rebate offer is continually extended, often lasting for more than 1 year or until a new model is introduced. Given the facts underlying the pricing of these monitors, we believed the retail prices of home blood glucose monitors less the available rebate amounts are reasonable measures of the market value of these devices. We are not aware of any manufacturer rebate that is not offered on a nationwide basis.

IV. Discussion of Public Comments on the Proposed Notice

In response to the January 1994 proposed notice, we received 8 timely items of correspondence. Comments were received from a variety of correspondents, including manufacturers of home blood glucose monitors, the Health Industry Manufacturers Association, the National Association of Retail Druggists, Blue Cross and Blue Shield of Illinois, pharmacies, and medical equipment suppliers. These comments and our responses are discussed below.

Comment: One commenter was confused by section II.B. of the proposed notice which deals with the applicability of the initial special payment limits (59 FR 758). In section II.B. of the proposed notice, we state that the initial limits ''would apply to standard home blood glucose monitors furnished on or after the effective date of the published final notice and before January 1, 1994.'' The commenter asked if the initial special payment limits would apply to new claims for standard home blood glucose monitors furnished in calendar year 1993 that are received after the date of the final notice.

Response: We proposed to apply the initial special payment limits in the proposed notice to standard home blood glucose monitors furnished before January 1, 1994. However, since we did not publish a final notice by January 1, 1994, no payments will be made based on these proposed special payment limits for any claims for standard home blood glucose monitors. Rather, the revised special payment limits presented in section V of this final notice will apply to standard home blood glucose monitors furnished to Medicare beneficiaries on or after the effective date of this final notice and before January 1, 1995. The special payment limits for CY 1995 will be equal to the 1994 special payment limits increased by the 1994 covered item update factor.

Comment: One commenter requested that we further define home blood glucose monitors with special features (HCPCS code E0609).

Response: The descriptor for HCPCS code E0609 is ''blood glucose monitor with special features (e.g., voice synthesizers, automatic timer, etc.).'' Section 60–11 of the Medicare Coverage Issues Manual (HCFA–Pub. 6) provides that there are ''blood glucose monitoring systems designed especially for use by those with visual impairments. The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors (also described in section 60–11). They differ by having such features as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable the visually-impaired to use the equipment without assistance.'' The special payment limits do not apply to monitors that are medically necessary and that

meet this definition. Suppliers are paid the lower of their actual charge or the DME fee schedule amount for monitors with special features.

Comment: Several commenters were concerned about our use of the prices listed in the Bruce mail order catalog as the basis of the special payment limits. Some commented that only a small percentage of home blood glucose monitors are obtained by Medicare beneficiaries through mail order catalogs; therefore, the pricing in the Bruce catalog does not reflect the retail prices of pharmacies and other suppliers of home blood glucose monitors.

Response: As we explained in the proposed notice (59 FR 756), we chose the Bruce catalog as the source of data for proposing special payment limits because it listed the largest number of home blood glucose monitors made by the largest number of home blood glucose monitor manufacturers. Prices comparable to the prices listed in the Bruce catalog are available in all localities from the various other mail order or retail outlets. We have reviewed numerous other sources of pricing and rebate information for the years 1986 through 1994 and have found this pricing and rebate information to be consistent with the pricing and rebate information listed in the corresponding editions of the Bruce catalog. The sources of pricing and rebate information that we surveyed include pharmacies and retail stores as well as mail order catalogs and mail order advertisements in Diabetes Forecast, a publication of the American Diabetes Association.

Comment: Some commenters maintained that the home blood glucose monitors represented in the Bruce catalog do not represent the entire home blood glucose monitor market. They noted that newer, technologically superior models of home blood glucose monitors such as the One Touch Basic, the AccuChek Easy, and the Glucometer Elite are not listed in the Winter 1993 edition of the Bruce catalog and therefore are not included in the data used in establishing the special payment limits for code E0607.

Response: In the proposed notice, we estimated that the six monitors listed in the Bruce Catalog accounted for approximately 90 percent of the market. Prices comparable to the prices listed in the Bruce catalog are available in all localities from other mail order catalogs and retail outlets.

If 1993 pricing and rebate information for the One Touch Basic, AccuChek Easy, and Glucometer Elite monitors was added to the data used in establishing the special payment limits for code E0607, the result would be a decrease in the 1993 special payment limit of $57. The One Touch Basic monitor and the AccuChek Easy monitor are both priced less than the One Touch II and AccuChek III monitors, the models that appear in the Winter 1993 edition of the Bruce catalog. The current net price of the Glucometer Elite monitor, which was introduced to the market in 1993, is approximately $60 (the retail price is approximately $125 and a manufacturer rebate of $65 is currently available).

Comment: One commenter, a supplier of home blood glucose monitors, suggested that we use its retail price of $76.69 as the special payment limit for code E0607. The supplier submitted an invoice dated February 1, 1994, to show that its cost per unit was $51.13 for a One Touch Basic monitor and stated that the proposed 1993 special payment limit of $57 would only allow it a 10-percent profit. Likewise, a manufacturer of home blood glucose monitors, suggested that we use $76, a median calculation based on average retail pricing for certain independent drug stores and DME suppliers, as the special payment limit for code E0607, while another manufacturer of home blood glucose monitors suggested that we use the Average Wholesale Price (AWP) of home blood glucose monitors as the special payment limit for HCPCS code E0607. The commenter defined AWP as the price the distributor charges the retailer for the product.

Response: These suggested amounts do not account for available manufacturer rebates; therefore, they are not indicative of the actual charge for the equipment in accordance with long-standing Medicare payment policy. Medicare payment for DME is equal to the lesser of the actual charge for the equipment (less the rebate amount) or the fee schedule amount.

On February 1, 1994, the manufacturer of the One Touch Basic monitor that the commenter obtained at a cost of $51.13 offered a $25 rebate paid directly to the supplier of the monitor. The cost of the monitor less the rebate is therefore $26.13. In this case, the 1994 special payment limit of $58.71 would allow for a 125 percent profit for the supplier.

Comment: One commenter maintained that a uniform special payment limit does not take into account the cost of doing business and the cost of living in different areas of the United States. The commenter stated that a payment ''floor'' and payment ''ceiling'' would be more appropriate.

Response: The average of the shipping and handling charges listed in the Bruce catalog is $7. This amount is included in the special payment limits for purchased new home blood glucose monitors, and represents a proxy for expenses incurred by retail stores that supply home blood glucose monitors. We reiterate that we are confident that prices comparable to the prices listed in the Bruce catalog are available in all localities from the various other mail order or retail outlets. An additional allowance of $8 is included in the special payment limit for new home blood glucose monitors furnished in Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands.

Each special payment limit established in this notice for code E0607 is an upper payment limit or ''ceiling.'' Lower payment limits, or ''floors,'' will not be established for code E0607; however, if the actual charge for the monitor is less than the special payment limit, then the Medicare payment is equal to the actual charge less any unmet deductible or coinsurance amounts.

Comment: Several commenters were concerned about our use of manufacturer rebate information in proposing special payment limits for code E0607. This issue was addressed at the supplier consultation meeting held on June 15, 1993 and was discussed in the proposed notice (59 FR 757). The commenters argued that the rebate programs are temporary and therefore should not be considered when developing special payment limits for code E0607. In addition, some manufacturers of home blood glucose monitors commented that their companies and other manufacturers recently developed and implemented costly new rebate programs whereby the rebate is paid directly to the supplier of the monitor. This new program would allow the supplier to deduct the amount of the rebate from the claim submitted to Medicare for payment. These manufacturers believe that it is therefore no longer necessary to consider manufacturer rebate information when determining special payment limits for home blood glucose monitors.

Response: As we stated in the proposed notice (59 FR 756), manufacturer rebates for home blood glucose monitors are widespread and have been available for several years. The fact that some manufacturers have incurred expenses in order to implement revised rebate programs indicates that manufacturer rebates for home blood glucose monitors will continue. In addition, we are not aware that all manufacturers will implement

programs to send the amount of the rebate to the supplier rather than to the beneficiary. We would still have no way of knowing in all instances if the charge submitted by the supplier included the manufacturer's rebate unless the supplier clearly marked and deducted an amount for the manufacturer's rebate. We believe the special payment limits for HCPCS code E0607 accurately reflect the maximum net costs incurred by non-Medicare patients who purchase or rent home blood glucose monitors (the supplier's charge less the manufacturer's rebate).

Comment: One commenter stated that the prices listed in the Bruce catalog do not reflect the time spent by suppliers on teaching patients how to use the monitors.

Response: As we noted earlier, the special payment limit of $58.71 exceeds most net prices that we have reviewed. The prices charged by suppliers generally include the cost of all services necessary to ensure the proper use of the home blood glucose monitor. This service includes teaching a beneficiary how to use the monitor. Therefore, the special payment limit amount of $58.71 should also include the cost for any time spent by a supplier in assisting a beneficiary. The pricing information that we reviewed included prices obtained from pharmacies and other retail store outlets. In addition, 5 of the 6 monitors listed in the Bruce catalog include either an instruction manual or instructional audio or video cassettes that explain how to use the monitors.

Comment: Several commenters stated that the special payment amounts are too low and would result in a negative impact on beneficiary access to standard home blood glucose monitors.

Response: This issue was discussed in section III.B. of the proposed notice (59 FR 759) and in section VI.B. below.

V. Provisions of the Final Notice

The following special payment limits represent a 3-percent increase over the limits published in the proposed notice and apply to standard home blood glucose monitors furnished to Medicare beneficiaries on or after the effective date of this final notice and before January 1, 1995:

- For a new monitor furnished in the continental U.S., the upper payment limit will be $58.71. In Alaska, Hawaii, Puerto Rico, and the Virgin Islands, the upper payment limit will be $66.95.
- For a used monitor, the upper payment limit will be 75 percent of the special payment limit for a purchased new monitor. For CY 1994, the special payment limit for a purchased new home blood glucose monitor furnished in the continental U.S. will be $58.71; the special payment limit for a used monitor will be $44.03.
- For a rented monitor, the special payment limit will be equal to 10 percent of the special payment limit for a purchased new monitor. For CY 1994, the special payment limit for a purchased new home blood glucose monitor will be $58.71; the monthly special payment limit for a rented monitor will be $5.87. The total payment for a rented monitor may not exceed the lower of the actual charge or the special payment limit for the purchase of the monitor.
- For each calendar year after 1994, the special payment limits will be equal to the special payment limits for the preceding calendar year increased by the covered item update factor for the calendar year during which the limits will apply. The covered item update factor is generally equal to the change in the CPI–U for the 12-month period ending June 30 of the preceding year.

VI. Regulatory Impact Statement

A. Introduction

This final notice will reduce unnecessary Medicare program expenditures for standard home blood glucose monitors. Currently, payment under the Medicare program for home glucose monitors is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. Under this final notice, payment for the remainder of CY 1994 will be equal to 80 percent of the lesser of the actual charge or the appropriate special payment limit listed in this notice.

We are establishing special payment limits for the remainder of CY 1994 for a purchased new home blood glucose monitor for Medicare beneficiaries of $58.71 if the monitor is furnished within the continental U.S. and $66.95 if furnished in Alaska, Hawaii, Puerto Rico, or the Virgin Islands.

During CY 1993, the Medicare program made payments to suppliers of approximately $17 million for approximately 130,000 home blood glucose monitor services of which 89,585 were purchased new home blood glucose monitors. We estimate that imposing special payment limits for purchased new home blood glucose monitors will produce savings of approximately $5 million annually, or $25 million from FY 1995 through FY 1999. Since purchased new home blood glucose monitors account for approximately 92 percent of Medicare expenditures for home blood glucose monitors, we anticipate negligible savings due to our reduction of payment for used or rented home blood glucose monitors.

B. Regulatory Flexibility Act

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a notice will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all suppliers and manufacturers of home blood glucose monitors are considered to be small entities.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

In determining whether to adjust payment rates for standard home blood glucose monitors, we considered the potential impacts on quality, access, and beneficiary liability of the adjustment, including the likely effects on assignment rates and participation rates of suppliers (as required by section 1842(b)(8)(C) of the Act).

This notice will affect suppliers of standard home blood glucose monitors. Their total Medicare payments could be reduced by the amount of the estimated savings. Suppliers can choose the option of accepting assignment, which means they agree to accept Medicare's approved amount as payment in full. As a consequence of our reducing payments for code E0607, the number of suppliers accepting assignment of beneficiary claims for Medicare payment for this code may decrease. These suppliers may choose instead to charge beneficiaries the full difference between the amount charged and the lower Medicare payment. Also, the number of suppliers who elect to become ''participating suppliers'' may decrease as a result of reduced payments for code E0607. Under the Medicare participation program, a supplier that decides to become a ''participating supplier'' must agree to accept assignment for all covered services furnished to Medicare beneficiaries. Participating suppliers benefit by being listed in the Medicare Participating Physician/Supplier Directories, known as Medpards, which are compiled by the Medicare carriers and furnished to various senior citizen

groups. A Medicare beneficiary can obtain the Medpard for his or her State from the Medicare carrier.

Suppliers who do not accept assignment and charge more than the Medicare-approved amount can collect the actual charge minus Medicare payment from the beneficiary. Therefore, beneficiaries who receive services from suppliers who do not accept assignment are exposed to greater financial liability than those who receive services from a supplier taking assignment. As a result, Medicare beneficiaries may choose to deal with participating suppliers or purchase less expensive home blood glucose monitors in order to reduce their financial liability.

Manufacturers of more expensive home blood glucose monitors may be affected if, as a result of this notice, suppliers choose to provide less expensive monitors or Medicare beneficiaries decide to purchase less expensive monitors. We expect that this notice will have minimal effects on the quality of monitors furnished to beneficiaries or on beneficiary access to quality monitors. As we demonstrated in the proposed notice, four of the six home blood glucose monitors listed in the Bruce Medical Supply catalog could be purchased in CY 1993 from anywhere in the continental U.S. for less than $57.

Though the decrease in the allowed limit from $185.79 (the 1994 fee schedule ceiling) to $58.71 for monitors purchased in the continental U.S. appears large, the net decrease is not large, given the size and prevalence of the rebates manufacturers have been refunding to beneficiaries. Three of the five manufacturers are giving rebates ranging from 45 percent to 67 percent of the purchase price. In addition, the glucose test strips used with the monitors are manufactured to be used with a specific brand of monitor. The 1994 fee schedule ceiling for blood glucose test strips, per 50 strips, is $37.41 or $.75 each and a beneficiary may use 4 or more each day. Therefore, once the beneficiary obtains a home blood glucose monitor, Medicare could pay an additional $90 each month the beneficiary uses the medically necessary monitor. The income generated in 1 month from the sale of the test strips could exceed the total income generated from the sale of the monitors. A manufacturer has an enormous incentive to promote the sale of its brand of monitors in order to ensure the future sale of its brand of test strips. For these reasons, we believe that manufacturers and suppliers will continue to provide their services to Medicare beneficiaries.

If a manufacturer's rebate is not reported on a Medicare claim for code E0607 and the beneficiary subsequently mails in the rebate form and receives the rebate, then the beneficiary receives a kickback in the amount of the rebate and the Medicare program is not benefiting from the rebate. This notice will effectively eliminate some of the kickback that beneficiaries may receive from manufacturer rebates that are not reported on Medicare claims for code E0607.

This notice may eliminate some of the manufacturer's incentive to provide beneficiary rebates. However, because a manufacturer realizes more income from the cumulative sale of its test strips than the one-time sale of a monitor, there remains a strong incentive to offer the beneficiary inducements to purchase its monitor. If the inducement involves a rebate or discount, that price reduction must be reported to the Medicare program by the supplier. The failure to disclose such discounts may implicate the Medicare anti-kickback statute. Medicare payment for DME is based on the lower of the actual charge (less any rebate amount) or the fee schedule amount.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

IV. Paperwork Reduction Act

This notice does not impose any information collection requirements. Consequently, it need not be reviewed by the Executive Office of Management and Budget under the authority of the Paper Reduction Act of 1980 (44 U.S.C. 3501 through 3511).

(Section 1834(a)(10)(B) of the Social Security Act (42 U.S.C. 1395m(a)(10)(B)); 42 C.F.R. 405.502(g))

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 5, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Donna E. Shalala,

Secretary.

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National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences; Notice of Meeting of the Fogarty International Center Advisory Board

Pursuant to Public Law 92–463, notice is hereby given of the twenty-ninth meeting of the Fogarty International Center (FIC) Advisory Board, February 7, 1995, in the Lawton Chiles International House (Building 16), at the National Institutes of Health.

The meeting will be open to the public from 8:30 a.m. to noon. The agenda will begin with a report by the Director, FIC. Presentations will include a report on the role of the NIH ombudsman; the December meeting of the Advisory Committee to the Director, NIH; and a report by the Director, NIH, on the present priorities of the Office of the Director. There will also be a report on new directions for the Scholars-in-Residence Program and a presentation on the FIC Young Investigator Award.

In accordance with the provisions of sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public from 1:15 p.m. to adjournment for the review of applications to the International Research Fellowship and Senior International Fellowship, nominations to the Scholars-in-Residence Program, and proposals for Scholar's conferences.

Paula Cohen, Committee Management Officer, Fogarty International Center, Building 31, Room B2C08, National Institutes of Health, Bethesda, Maryland 20892 (301–496–1491), will provide a summary of the meeting and a roster of the committee members upon request.

Irene Edwards, Executive Secretary, Fogarty International Center Advisory Board, Building 31, Room B2C08, telephone 301–496–1491, will provide substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Cohen at least 2 weeks in advance of the meeting.